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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants: Christine Carlucci and Gerard Carlucci

For: Medical Tubing Securing Device

Serial No.: 09/930,398

Filed: August 15, 2001

Group: 3761

Atty Docket: 262-801

TRANSMITTAL OF APPEAL BRIEF

Mail Stop Appeal Brief - Patent
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Enclosed are the following:

1. Appeal Brief in triplicate

2. Form PTO 2038 authorizing the charge of $340.00 to the account designated therein. Should this amount be insufficient, kindly charge the appropriate amount to the designated account.

October 18, 2004

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APPEAL BRIEF

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Real parties in interest

Christine Carlucci and Gerard Carlucci

Related appeals and interferences

A first appeal brief was filed on September 9, 2003, appealing the final rejection of claims 1-14 in this case. In response, on November 28, 2003, a new office action issued, treating the appeal brief as a request for reconsideration of the finality of the rejection and withdrawing the finality of the final action. In the November 28, 2003 office action, the examiner then rejected claims 1-14 under prior art not previously cited against the claims. Appellant argued against the rejections in a response submitted on February 25, 2004. The examiner then issued a final action on May 18, 2004, to which this appeal is taken.

Status of claims

Claims 1-14 are all the claims in the case. Claims 1-14 were rejected in the final action mailed on May 18, 2004. Appellants appeal the rejection of claims 1-14.

Status of amendments

No amendment was filed subsequent to final rejection.

Summary of invention

This application discloses an apparatus designed to comfortably and efficiently maintain medical tubing in place on the head of a hospitalized patient. Referring to Fig. 2, the apparatus comprises a substantially circular member (15) fabricated from an elastic material, with one or more closed loops (14) integrated therein. The circular member engages the head of the patient and the elastic property of the circular member serves to secure it to the head of the patient comfortably without causing constriction of blood vessels or skin irritation. Preferably, the circular member is covered with soft, non-irritating material to maximize comfort. The integrated loops can receive medical tubing such as that associated with continuous positive airway pressure (CPAP) delivery systems, nasal- and oral-gastric feeding tubes, pH probes, oral suction tubes, gastric secretion tubes and tubes used for intravenous drug delivery. Specification, page 3, lines 6-18.

This invention is particularly useful in the cases of infants born prematurely. Such patients have delicate skin which is easily irritated and bruised. Moreover, the skulls of prematurely born infants are soft and malleable and can be deformed by the use of the attachment devices of the prior art. The present inventive apparatus avoids the problems of the prior art by providing a soft and flexible attachment having no hard or sharp protrusions. It will therefore not bruise or otherwise harm the vulnerable skin or skull of a very young infant.

Issues

Whether it was error to reject claims 1-4, 6-9 and 11-14 as anticipated by United States Patent 5,411,484 to Shattuck ("the Shattuck patent") in view of United States Patent 5,154,690 to Shiono ("the Shiono patent") when the Shattuck patent does not disclose the use of an elasticized band, which is a limitation in all the rejected claims, and the Shiono patent fails to show that elasticity is an inherent characteristic of tricot?

Whether it was error to reject claims 5 and 10 as obvious over the Shattuck patent in view of the Shiono patent and in further view of US Patent 3,878,849 to Muller ("the Muller patent") when those references, taken alone or together, did not teach or suggest the use of an elasticized band for holding medical tubing to the body?

The Background and Utility of the Present Invention

Prior art devices for securing medical tubing to the head of a hospitalized patient are discussed in the specification at pages 1-2. There are numerous drawbacks to these various devices. Some are prone to slippage. Slippage is generally corrected by the use of tape which itself can cause allergic reaction or otherwise irritate the skin. The alternative to tape is to tighten the apparatus, which for patients such as premature infants can be harmful since their skulls are soft and deformable. Some of the prior art devices are prone to inadvertent disassembly of the ties, buckles, or hook-and-eye closures that are utilized to hold and secure the medical tubing.

The present invention overcomes these drawbacks by utilizing a band of soft, elastic material to encircle the head. Portions of the band are gathered to form closed loops through which tubing may be passed and thereby secured to the head. The inventive device thus does not irritate the skin, compress the skull or blood vessels, or incorporate bulky or dangerous components which can cause discomfort or injury. In addition, by virtue of the tubing loops being closed, the tubing cannot disengage from the securing device.

Referring to FIGS. 1, 2, 4, the device of the instant invention is denominated by numeral 12. Device 12 is made of a band of an elasticized, absorbent fabric and can be covered with soft, non-irritating material to maximize comfort. Device 12 includes a relatively large circular section 15 which will fit snugly to the head of the patient when slipped over the top of the skull. At least one loop 14 is adjacent to section 15, through which medical tubing such as that associated with a CPAP apparatus 10 can be inserted. As shown in FIGS. 2, 3, and 4, loop 14 can be formed by joining two points 16a and 16b, along the width w of the band, such as by stitching 13 or other non-disengagable fastening technique.

As shown by reference to FIG. 1, CPAP apparatus 18 is secured to the head of a patient through use of the device 12. Apparatus 12 extends around the patient's head, above the ears. The tubing portions 10 of the CPAP apparatus are passed through loops 14 and the nasal cannulae 19 are positioned so as to fit into the nose 20 of the patient. There is no danger of the tubing portions pulling away from device 12, since loops 14 are closed.

Used as illustrated, device 12 is comfortably yet firmly seated on the patient's head and securely anchors medical tubing to the head, without the need for potentially injurious components. The device is of simple manufacture, and can be produced in a cost-effective manner.

Claim 1 of the present invention reads as follows:

> A device to secure medical tubing to a body comprising a one-piece fabric band having at least a first closed loop and a second closed loop, wherein the first closed loop fits elastically around a portion of the body and second closed loop is capable of receiving and holding medical tubing close to the body.

All the claims of the application are limited to a one-piece fabric band having a closed loop which fits elastically around a portion of the body.

Argument

A. The Examiner's Rejection Under §102 Was Erroneous Because the Shattuck Patent Does Not Disclose the Use of An Elasticized Loop

The examiner rejected claims 1-4, 6-9, and 11-14 as anticipated by the Shattuck patent in view of the Shiono patent. This was erroneous.

The rejected claims are all limited to a one-piece fabric band having a closed loop which fits elastically around a portion of the body. The Shattuck patent does not disclose an elastic loop, but instead discloses an open fabric strip having a loop at one end and a velcro attachment at the other end. The loop is placed over tubing inserted into the head and the free end is pulled taut and attached by velcro to the fabric strip in order to maintain a frictional hold on the head. Col. 4, lines 8-13.

The examiner cites col. 7, lines 48-54, the Shiono patent to support the position

that tricot, the fabric disclosed in Shattuck, is inherently elastic. This reliance, however, is misplaced. The cited portion of the Shiono patent refers to a tricot fabric which has been modified to include an elasticized thread. *Id.* As seen by standard references, the definition of tricot is "a plain warp-knitted fabric (as of nylon, wool, rayon, silk, or cotton) with a close *inelastic* knit and used especially in clothing (as underwear). Emphasis supplied. Merriam-Webster Online Dictionary at http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=tricot. There is no teaching in the Shiono patent that tricot is elastic. Shiono only teaches that one may modify tricot to obtain an elasticized fabric suitable for providing pressure treatment for epicondyle disease.

The Shattuck patent explicitly acknowledges the lack of elastic characteristic by the suggestion at col. 4, lines 5-8 that the "inner surface 9 of loop 3 may be optionally treated with a non-slip material in order to further facilitate grip strength."

Accordingly, the Shattuck patent does not teach a closed elastic loop which fits around a portion of the body, as claimed by the rejected claims, and therefore cannot anticipate the claims of the present invention. Reversal of the rejection of these claims is respectfully requested.

B. The Examiner's Rejection Under § 103(a) of Claims 5 and 10 Was Erroneous Because the Shattuck, Shiono and Muller Patents Taken Alone or in Combination Do Not Teach or Suggest the Use of a One-Piece Elasticized Fabric Band

The examiner rejected claims 5 and 10 as obvious over the Shattuck patent in view of the Shiono and Muller patents. This was erroneous. Shattuck teaches the use

of a fabric strip which can be frictionally tightened against a body portion so that medical tubing may be held close to the body. The Shattuck patent does not disclose or even suggest that the use of elastic material would be useful in this regard. Shiono teaches the use of elasticized fabric for different, unrelated purpose, i.e., for providing pressure therapy to treat disease. Accordingly, taken together, Shattuck and Shiono do not suggest the subject matter of claims 5 and 10, which are dependent on claims 1 and 6, respectively, which recite that the closed loops fit elastically around a portion of the body.

The examiner relies on the Muller patent for teaching a device for holding a medical tubing to a body, wherein the device has closed loops formed with stitching 42. This teaching does not, however, teach or suggest the use of a closed elastic loop that fits elastically around a portion of the body. The fabric strip of the Muller patent is adjustable with a high friction layer on one of its faces for engaging the patient's skin so that the strap may be relatively loosely secured about the body portion while being firmly retained thereon by the high friction layer. While the fabric of the Muller patent may be elastic, the fit to the body is not due to elasticity but to the frictional engagement of the friction layer to the skin.

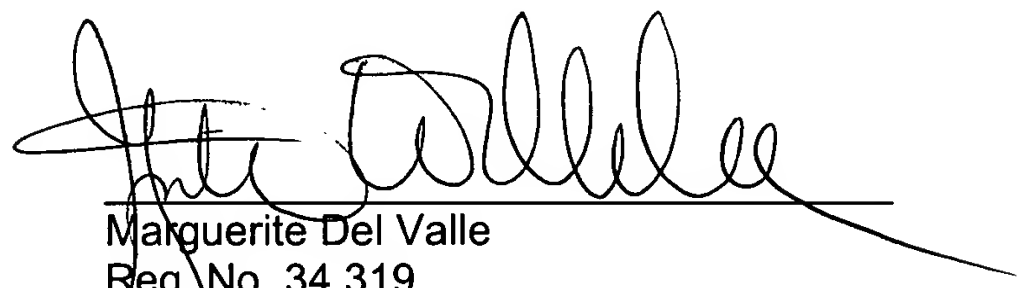
Because there is no teaching or suggestion to support the combination on which the rejection is based, it is respectfully submitted that the rejection of the claims was erroneous and should be reversed.

Conclusion

In view of the foregoing, it is respectfully requested that the rejection of the claims be reversed, and that the claims be allowed to proceed to issue.

October 18, 2004

Respectfully submitted,



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Appendix: Claims involved in the appeal

1. A device to secure medical tubing to a body comprising a one-piece fabric band having at least a first closed loop and a second closed loop, wherein the first closed loop fits elastically around a portion of the body and the second closed loop is capable of receiving and holding medical tubing close to the body.

2. A device according to claim 1 wherein the portion of the body around which the first closed loop fits is a head.

3. A device according to claim 1 wherein the fabric band is covered with a soft, non-irritating material.

4. A device according to claim 1 wherein the fabric band is at least partially lined with a friction creating material.

5. A device according to claim 1 wherein the closed loops are formed by stitching.

6. A device to secure medical tubing to a body comprising a one-piece fabric band having a first closed loop, a second closed loop and a third closed loop, wherein the first closed loop fits elastically around a portion of the body and the second and third closed loops are capable or receiving and holding medical tubing close to the body.

7. A device according to claim 6 wherein the portion of the body around which the first closed loop fits is a head.

8. A device according to claim 6 wherein the fabric band is covered with a soft, non-irritating material.

9. A device according to claim 6 wherein the fabric band is at least partially lined with a friction creating material.

10. A device according to claim 6 wherein the closed loops are formed by stitching.

11. A device to secure medical tubing to a body comprising a one piece fabric band having a width wherein stitching along the width joins portions of the band to form a first closed loop, a second closed loop and a third closed loop, and wherein the first closed loop fits elastically around a portion of the body and the second and third closed loops are capable of receiving and holding medical tubing close to the body.

12. A device according to claim 11 wherein the portion of the body around which the first closed loop fits is a head.

13. A device according to claim 11 wherein the fabric band is covered with a soft, non-irritating material.

14. A device according to claim 11 wherein the fabric band is at least partially lined with a friction creating material.